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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,558

06/17/2005

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09/03/2008

EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,558	Applicant(s) HILLMAN, YITZCHAK	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-108 and 113-125 is/are pending in the application.
- 4a) Of the above claim(s) 100-108 and 118-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113-117 and 122-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/29/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group XX (claims 113-117 and 122-125) in the reply filed on May 29, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and made final.

Claims 100-108 and 118-121 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 29, 2008.

Specification

The disclosure is objected to because of the following informalities: Page 67 line 31 recites application number “@@@”, rather than an appropriate application number.

Appropriate correction is required.

Please note, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 113-117 and 122-125 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

The instant claims are drawn to administration of an AMP or AMP-like molecule to treat “a disease”, where dependent claims define the administration as either direct, or via expression within the subject. The AMP/AML is defined in dependent claims a defensin or LL-37.

The specification provides TABLE 1 (page 25):

Table 1. AMPs/AMLs and cognate cell receptors, and diseases associated with interaction therebetween

AMP/AML	Receptor	Receptor-expressing cells	Disease
LL-37	EGFR, FPRL1	Monocyte, dendritic cell, T cell, neutrophils, eosinophils, leukocytes, epithelial cell, endothelial cells	Psoriasis, rheumatoid arthritis (RA), atopic dermatitis, contact dermatitis, chronic hepatitis, inflammatory bowel disease (IBD), allergy, B cell malignancies, hepatocellular carcinoma, pancreatic adenocarcinoma and others
beta-defensin-2	Toll Like receptor-4	Dendritic cells	
beta-defensin-2	Toll-like receptor-2		
beta defensin-1 beta defensin-2	CC-chemokine receptor-6 (CCR6)	Hematopoietic cells, dendritic cells,	Psoriasis, RA, atopic dermatitis, contact dermatitis, chronic hepatitis, IBD, allergy, B cell malignancies, hepatocellular carcinoma, pancreatic adenocarcinoma and more
defensin-5		Intestinal mucosa	Crohn's disease
adrenomedullin	LL and calcitonin receptor-like receptor (CRLR)	gastric epithelial cells	IBD, allergy, hepatocellular carcinoma, and more

The specification states, “**The molecule capable of inhibiting activation or ligand binding of the AMP/AML may advantageously inhibit binding of a receptor expressed on cell**, such as a leukocyte, which binds the AMP/AML to inhibit a biological process mediated by binding of the AMP/AML to the receptor. Examples of such AMPs/AMLs and cognate receptors thereof are shown in Table 1.” (emphasis added, page 25).

In looking to the examples, antibodies are relied upon for the treatment. Furthermore, the specification additionally states, “As described above, **preventing binding of AMPs/AMLs to cognate receptors may be used to inhibit a biological process mediated by binding of the AMP/AML to the receptor**. Over 50 AMPs/AMLs and over 20 receptors thereof are involved disease pathogenesis, therefore inhibiting correct target combinations of ligand and receptors is

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essential for treatment of such diseases. Examples of such AMPs/AMLs and cognate receptors thereof, and the types of diseases which can be treated using this approach are shown in Table 1.” (emphasis added, page 83).

From the disclosure it is clear that inhibition of the AMP/AML binding with the cognate receptor is required to treat the condition, and not administration/expression of the AMP/AML, which are discussed in the specification as an underlying effector of the condition, stating, “Therefore, down regulating AMPs can be used for preventing age related diseases.” (page 82).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 113-117 and 122-125 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is inoperative for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the specification lacks any specific examples of using the AMPs/AMLs (defensins or LL-37) to treat any condition, having only examples of using antibodies to inhibit the AMPs and thereby treating the disease. The specification provides that these AMPs/AMLs are postulated to be an underlying contributor of the various conditions, such that inhibition of, e.g. LL-37 interaction with the cognate receptor, is hypothesized as a means to treat various conditions, e.g. psoriasis. Thus, the artisan would not be able to practice the invention commensurate in scope with the claims without undue experimentation.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654